

"predetermined" in this case does not imply any particular amount of liquid. Rather, it indicates that the aerosol container is one which releases a fairly precise amount each time it is actuated, so that the patient receives a desired amount.

In claim 18, it is thought that the conventional pharmaceutical carrier substances are known and need not be defined precisely. In this case, the active ingredient, azelastine, is put up in a powder. The kinds of inert components which are used to produce a pharmaceutical powder are known. While the terminology is broad, it is submitted that it is not indefinite.

Applicants respectfully traverse the rejection of claims 11 and 18 as lacking an enabling disclosure. The specification clearly teaches that it is possible to put up the claimed medicines in pharmaceutical powders. The concentration of active ingredient in the powders is disclosed at page 5, last three lines. The particle size is disclosed at page 10, lines 14-16. It is submitted that this provides sufficient information for a person skilled in the art to make the claimed compositions in the form of powders.

Applicant respectfully requests reconsideration of the rejection of claims 1, 6, 7, 9, 10, 11 and 12 as anticipated under 35 U.S.C. 102 over Vogelsang. These claims recite that azelastine is applied "directly to nasal tissues or to the conjunctival sac of the eye", and this process step is not disclosed in Vogelsang.

In discussing this ground of rejection on page 3 of the Office Action, the Examiner has not cited any portion of the reference which teaches this step. The comment that Vogelsang discloses the use of azelastine in a pharmaceutical

preparation that can be administered in usual embodiments such as tablets, etc. does not support an assertion that the reference discloses the specific form of administration claimed in this application, within the context of 35 U.S.C. 102. That provision of the patent statute is quite specific in requiring that the reference actually disclose the process which is claimed. A similar comment can be made with regard to the Examiner's contention that aerosol administration is disclosed in the reference, with the further comment that the reference does not disclose aerosol administration of azelastine (see discussion below).

The following are some of the legal authorities which define the scope of 35 U.S.C. 102.

Ex parte Meyer, 213 USPQ 588, 590

To anticipate a claimed invention, all limitations in the claims must be found in the reference since the claims measure the invention....Moreover, a rejection under 35 U.S.C. 102(e) necessarily implies that the invention is not new, i.e., that there is no difference between what is claimed and what is disclosed in the prior art. (Emphasis added.)

Ex parte Stubbs, 149 USPQ 641

Claims 7 and 8 are rejected as unpatentable over Jones et al. It is stated in the answer that this rejection is under 35 USC 102. However, it is apparent from the Examiner's position as to these claims that the rejection can only be under 35 U.S.C. 103 because the claims include a limitation that is not shown in the reference.

In re Kalm, 154 USPQ 10

A rejection under 35 U.S.C. 102(e)...necessarily implies that the invention sought to be patented has been described...that there are no differences between what is claimed and what is disclosed....

The reference simply does not disclose the step of administering azelastine "directly to nasal tissues or to the

conjunctival sac of the eye". Therefore, this ground of rejection is thought to be inappropriate.

Applicant also requests reconsideration of the rejection of the claims under 35 U.S.C. 103. Contrary to the Examiner's contention, it is submitted that Vogelsang does not disclose administering azelastine "directly to nasal tissues or to the conjunctival sac of the eye". The passages cited by the Examiner do not establish the contrary.

Column 1, line 57 discloses a category of active ingredients which include azelastine, and, as the Examiner has said, azelastine is specifically exemplified in the patent. However, this particular passage does not say anything about the mode of administration.

Column 6, line 65 which the Examiner has cited discloses various dosage forms, but, again, there is no disclosure of direct administration to nasal or eye tissues. While treatment of disorders of the skin and mucus membranes are mentioned, direct administration to nasal tissues and the conjunctival sac of the eye are not mentioned.

The Examiner has also referred to the disclosure of an aerosol, but applicant submits that the Examiner has misunderstood this disclosure. The reference does not teach putting up azelastine in an aerosol. The aerosol is used to administer histamine in a guinea-pig test. The Examiner has referred to Column 6, line 21 which is the heading for Table I. It refers to Histaminolytical activity in the histamine aerosol test on guinea-pigs. This test is described in Column 5, lines 49-63. In that test, the guinea pigs inhale an aerosol of histamine. The test compounds, such as azelastine, are administered "subcutaneously or orally" (column 5, line 58). Therefore, the disclosure of

aerosols in this reference is wholly unrelated to the use of aerosols in connection with the present invention.

The invention provides numerous advantages associated with other forms of administration. These are discussed on pages 1 and 2 of the present application. The Examiner has pointed to the declarations submitted previously, but of course these are concerned with a comparison with a different reference. These declarations show that azelastine is more effective than other active agents disclosed in the Engel reference which was cited previously. However, since the Vogelsang reference actually discloses azelastine, it raises entirely different issues.

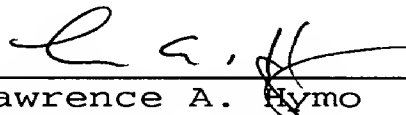
The only routes of administration actually disclosed in Vogelsang are subcutaneous (parenteral) and oral. There is no evidence that azelastine would be effective when applied directly to nasal tissues or to the eye. The advantages of the present invention relate to a different mode of administration, but there is no suggestion of them in this reference. This is reinforced by Examples 43-46 which relate to dosage units, i.e., tablets, dragees, suppositories and injection ampoules.

Finally, applicants request reconsideration of claims 13-17. The Examiner has shown that the various appliances covered by those claims are known and that they have been used to administer medications. There can be no doubt that these appliances are not broadly new as a way to administer medications. However, it is submitted that it would not have been obvious to put up azelastine in these kinds of appliances, because it was not obvious to administer azelastine to parts of the body for which these types of appliances are suited.

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For these reasons, it is submitted that the present invention is patentable, and that all informalities in the claims have been corrected. Favorable reconsideration of the claims and allowance are respectfully requested.

Respectfully submitted,
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